Docket No. 2016-4005

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	MILAN S. BLAKE, ET AL.	
Serial No.	:	08/231,229	Group Art Unit: 1818
Filed	:	April 21, 1994	Examiner: P. Achutamurthy
For	:	GROUP A STREPTOCOCCUS POLYSACCHARIDE IMMUNOGENIC COMPOSITIONS AND METHODS	

BOX AF
Assistant Commissioner For Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. §1.132 OF MACLYN McCARTY

I, Maclyn McCarty, declare:

1. I am Vice-President Emeritus of The Rockefeller University, New York, New York 10021. A copy of my Curriculum Vitae is attached as Exhibit 1.

2. I have read and understand the pending application as well as the Final Rejection in that application which was mailed on May 23, 1997. I have also read the publications cited by the Examiner in support of the grounds of rejection.

3. In the Final Rejection of May 23, 1997, I understand the Examiner to have rejected claims 3, 5-7, 9-12, 15, 16, 19-22, 24, 29-35, 37-43,45-53 and 55-66 under 35 U.S.C. §102

and 103 because the Examiner contends that the cited publications disclose or teach Group A streptococcal polysaccharide and its use to confer protection against infections by Group A streptococcal bacteria.

4. In my view, this application discloses that the group A streptococcal carbohydrate has potential for development as a preventive vaccine for streptococcal infections. While the carbohydrate has been known and studied in many laboratories for eighty years, it had been considered without potential as an immunizing agent for most of that period. As the authors accurately describe in the introduction to the application, they first obtained evidence for antibodies providing protection against infection by various types of group A streptococci in experiments first published in 1995. This is the first evidence of which I am aware that antibodies to the carbohydrate had this potential.

5. The application is designed to allow the development of a practical vaccine for prevention of streptococcal disease in human populations.

6. The history of active research on streptococci goes back to the last century, but that dealing with the individual components of the microorganism and their role in causing disease began in the third decade of this century with the pioneering work of Rebecca C. Lancefield at the Rockefeller Institute for Medical Research (now Rockefeller University). She

discovered the type-specific antigens - called M protein - and their importance in streptococcal infection, and showed that anti-M antibodies protected against infection. Since there are several dozen different types of group A streptococci, each with its own M protein and each requiring a different anti-M antibody for immunity, streptococcal sore-throat was a notoriously recurring disease and school age children had repeated attacks, each with a different specific type of organism. With advancing age the incidence of infection decreases, suggesting some broader form of immunity that is not type-specific. It was this fact that led the applicants to reexamine the possible role of antibodies to the group A carbohydrate.

7. Dr. Lancefield also discovered the group carbohydrates, and used rabbit antibodies to this streptococcal component to divide streptococci into several serological groups, identifying group A as the one involved in most human infections. She found no evidence for a protective effect of antibodies to the carbohydrate. I was associated with Dr. Lancefield for thirty-five years, as head of the Laboratory of Streptococcal Infections and associated clinical studies of Rheumatic Fever at Rockefeller. My studies on the group carbohydrate involved demonstrating that it was the major constituent of the bacterial cell wall and work on the composition and structure of the carbohydrate. This research was motivated by the possibility that the carbohydrate might conceivably be a factor in the

pathogenesis of rheumatic fever. I considered the issue of the possible role of anti-carbohydrate antibodies in protection against streptococcal infection to have been settled.

8. My view on this last point appeared in print as late as 1989. This was in a chapter on Streptococci that I wrote for the highly regarded textbook, *Microbiology* (B.D. Davis, R. Dulbecco, H.N. Eisen, & H.S. Ginsberg, Editors, 4th Edition, J.B. Lippincott, 1989). In this chapter (page 535) I began the section on Immunity with the following sentence: "Of the many varieties of antibodies that are generated in response to group A hemolytic streptococcal disease, only anti-M is known to protect the host against invasiveness of the organisms." None of the publications cited by the Examiner change my view that at the time the application was filed, those skilled in the art did not consider the Group A streptococcal polysaccharide to be relevant to conferring protective antibodies against infections by the Group A streptococcal bacteria.

9. There seems to be no question that the developments of the invention by applicants which relates to the activity of antibodies to group A polysaccharides are novel and worth pursuing for vaccine development.

10. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: November 24, 1997

Maclyn McCarty

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CURRICULUM VITAE

05/97

Maclyn McCarty, M.D.

Born: June 9, 1911 - South Bend, Indiana

Education: Stanford University - A.B., 1933
Johns Hopkins University - M.D., 1937

1937-40 Intern and Assistant Resident in Pediatrics at the Johns Hopkins Hospital, Baltimore, Maryland.

1940-41 Fellow in Medicine at New York University School of Medicine in laboratory of Dr. William S. Tillett.

1941 to present At The Rockefeller Institute for Medical Research (now The Rockefeller University), New York, NY.

1941-42 Fellow in the Medical Sciences of the National Research Council with Dr. O.T.Avery.

1942-46 Active duty (USNR) with Naval Medical Research Unit at the Rockefeller Institute.

1946-48 Associate of the Rockefeller Institute and Associate Physician to the Hospital

1948-50 Associate Menber and Associate Physician

1950-58 Member and Physician

1958-81 Professor

1960-74 Physician-in-Chief to the Hospital

1965-78 Vice President

1977-7/81 John D. Rockefeller, Jr. Professor

7/81 - Professor Emeritus

From 1946 to July 1981, head of laboratory concerned with biology of hemolytic streptococci and rheumatic fever.

1972-76 Adjunct Professor of Medicine, Cornell University Medical College.

Fields of Investigation:
Transformation of pneumococcal types and the genetic role of DNA; C-reactive protein; biology and immunochemistry of streptococci; nature of rheumatic fever.

Professional Societies:

American Academy of Arts and Sciences
American Association for the Advanacement of Science
American Association of Immunologists
American Pediatric Society
American Philosophical Society
American Society for Microbiology
Association of American Physicians
Harvey Society (Life Member)
Interurban Clinical Club
National Academy of Sciences
New York Academy of Medicine
Sigma Xi
Peripatetic Club
Transplantation Society
Infectious Diseases Society of America

Honors:

Alpha Omega Alpha
Phi Beta Kappa
Eli Lilly Award in Bacteriology and Immunology - 1946
The Johns Hopkins Society of Scholars - 1975
D.Sc. (honoris causa) Columbia University - 1976
D.Sc. (Honoris causa) University of Florida - 1977
John D. Rockefeller, Jr. Professorship, The Rockefeller University, 1977-81.
Waterford Biomedical Sciences Award of the Scripps Clinic and Research Foundation - 1977
Deutsche Gesellschaft für Hygiene und Mikrobiologie (Honorary Member) - 1978
Medal of the New York Academy of Medicine - 1979
American College of Physicians Award for achievement in medical science - 1980
Robert Koch Gold Medal, Robert Koch Stiftung, West Germany - 1981
Order of the Republic, 1st degree, Egypt - 1982
D.Sc. (honoris causa) The Rockefeller University - 1982
Order of San Carlos, Republic of Columbia - 1984
Commander's Cross of the Order of Merit of the Federal Republic of Germany -1984. (Der Deutsche Verdienst Kreuz)
D.Sc. (Hon.) - Medical College of Ohio - 1985
D.Sc. (Hon.) - Emory University - 1987
Jessie Stevenson Kovalenko Medal - Natl. Acad. Sci. - 1988
M.D. (Hon.) - University of Köln - 1988
D.Sc. (Hon.) - Wittenberg University (Ohio) - 1989
George M. Kober Medal - Assn. of Amer. Physicians - 1989
Wolf Prize in Medicine (Israel) - 1990
John Stearns Award for Lifetime Achievement in Medicine - The New York Academy of Medicine - 1993
Albert Lasker Special Public Health Award - 1994
Doctor of Humane Letters (Hon.) - Mt. Sinai Sch. Med. - 1995

Professional Activities:

American Heart Association (1968-1972)
Member of Policy and Affiliate Relations Committee

Armed Forces Epidemiological Board
Associate Member Commission on Streptococcal and Staphylococcal Diseases (1948-1972)

Assembly of Life Sciences, National Research Council
Member of Executive Committee (1974-1977)

Associated Universities, Inc.
Trustee (1978-1981)

Brookhaven National Laboratory
Member of Visiting Committee to Medical Department - 1970s

Biomedical Research Center for Infectious Diseases, Cairo, Egypt
Member of Advisory Board (1978-1983)

The Harvey Society
Secretary (1947-1950); President 1971-72)

Health Research Council of the City of New York (dissolved 1975)
Member, Allergy and Infectious Disease Panel
Chairman of Council (1972-1975)

Helen Hay Whitney Foundation
Scientific Advisory Committee
Member, 1956-1996
Chairman, 1963-1996
Vice President, 1964-present
Member. Board of Trustees, 1964-present.

Institute of Medicine, National Academy of Sciences
Charter Member

Massachusetta General Hospital
Member Scientific Advisory Committee (1967-1969)

National Academy of Sciences
Chairman, Section of Medical Sciences (1971-1974)
Member of Council (1973-1976)
Member of Report Review Committee (1974-1978)

New York Heart Association
President (1969-1971)
Chairman, Advisory Council on Research (1971-1873)
Member of Executive Committee (1969-1979)

New York Community Trust
Member, Disribution Committee (1966-1974)

Public Health Research Institute of City of New York
Board of Directors, 1965?-present; Chairman (1984-1992)
Research Council, 1965?-1980?: Ckairman (1969-1977)

R.J.Reynolds Industries
Member, Advisory Committee for Biomedical Research (1978-1989)

Society for Experimental Biology and Medicine
President (1974-1975)

Stanford University School of Medicine
Member of Visiting Committee (1964-1972)

Scripps Clinic and Research Fouondation, La Jolla, CA
Member of Advisory Board (1980-1982)

Sterling-Winthrop Research Institute
Member, Research Board (1973-1976)

C.V.Whitney Laboratory of Exptl. Marine Biol. and Med. (U. Fla.)
Member, Board of Scientific Advisors, (1977-1983)
World Health Organization (1966-1971)
Member, Expert Advisory Panel on Chronic Degenerative Diseases

Editorial Activities:

Editor, The Journal of Experimental Medicine, 1963-present
Associate Editor, The Journal of Immunology, 1962-1970
Member, Editorial Board, Infecton and Immunity, 1970-1981
Member, Editorial Board, Proceedings of the National Academy of Sciences, 1972-1977

Current Interests:

Research:
The biology of group A streptococci and the pathogenesis of rheumatic fever.

Organizational:
Board of Trustees, Helen Hay Whitney Foundation

Board of Directors, Public Health Research Institute

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May 1997

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03/95

Maclyn McCarty, M.D.

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4. The relation of a somatic factor to virulence of pneumococci (with C.M.MacLeod), *J. Clin. Invest.* (Abstract), 1942, 21, 647.

5. Studies on the chemical nature of the substance inducing transformation of pneumococcal types. Induction of transformation by a desoxyribonucleic acid fraction isolated from pneumococcus type III (with O.T.Avery and C.M.MacLeod), *J. Exp. Med.*, 1944, 79, 137-158.

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8. Studies on the chemical nature of the substance inducing transformation of pneumococcal types. II. Effect of desoxyribonuclease on the biological activity of the transforming substance (with O.T.Avery), *J. Exp. Med.*, 1946, 83, 89-96.

9. Studies on the chemical nature of the substance inducing transformation of pneumococcal types. III. An improved method for the isolation of the transforming substance and its application to pneumococcus types II, III, and VI (with O.T.Avery), *J. Exp. Med.*, 1946, 83, 97-104.

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11. Biochemical studies of the environmental factors essential in transformation of pneumococcal types (with H.E.Taylor and O.T.Avery), *Cold Spring Harbor Symposia Quant. Biol.*, 1946, 11, 177-183.

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